

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	M.D.L. No. 1456
LITIGATION)	Civil Action No. 01-12257-PBS

MEMORANDUM AND ORDER

February 24, 2004

Saris, U.S.D.J.

I. INTRODUCTION

In this massive proposed class action, Plaintiffs allege that forty-two pharmaceutical companies fraudulently overstate the published "average wholesale prices" ("AWP") of many of their prescription drugs, which results in inflated payments for such drugs by consumers and beneficiaries of the federal Medicare Part B program (through co-payments), private health and welfare plans, health insurers, self-insured employers and other end-payers for prescription drugs.¹ They have identified 321 drugs

¹ The Amended Complaint names eleven plaintiffs, including five ERISA-qualified employee benefit plans, a voluntary employee benefit plan and five associations. It names the following companies as defendants (corporate groupings are separated by semicolon): Abbott Laboratories; Amgen Inc.; "AstraZeneca," which includes Zeneca, Inc., AstraZeneca US, and AstraZeneca Pharmaceuticals L.P.; "The Aventis Group," which includes Aventis Pharmaceuticals, Inc., Hoechst Marion Roussel, Inc., and Aventis Behring LLC; "Baxter," which includes Baxter International Inc. and Baxter Healthcare Corporation; Bayer Corp.; "The Boehringer

with allegedly inflated prices.

On May 13, 2003, the Court allowed in part a motion to dismiss the original master consolidated complaint. See In re Pharm. Indust. Average Wholesale Price Litig., 263 F. Supp. 2d 172, 178-80 (D. Mass. 2003) (Saris, J.) (Pharm. I). The Court assumes close familiarity with that opinion, which sets forth the factual background of the allegations as well as the appropriate legal standards. In response to that opinion, Plaintiffs have filed a 297-page amended master consolidated complaint ("AMCC"), which asserts violations of the federal racketeering statute, eleven consumer fraud statutes and the antitrust laws.² Again,

Group," which includes Boehringer Ingelheim Corp., Ben Venue Laboratories Inc. and Bedford Laboratories; B. Braun of America, Inc.; "The BMS Group," which includes Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp., and Apothecon, Inc.; Dey, Inc.; "The Fujisawa Group," which includes Fujisawa Healthcare, Inc. and Fujisawa U.S.A., Inc.; "The GSK Group," which includes GlaxoSmithKline, P.L.C., SmithKline Beecham Corp., and Glaxo Wellcome, Inc.; Hoffman-LaRoche, Inc.; Immunex Corp.; "The Johnson and Johnson Group," which includes Johnson & Johnson, Centocor, Inc., Janssen Phamarceutical Products, L.P., McNeil-PPC, Inc., and Ortho Biotech; Novartis Pharmaceuticals Corp.; Pfizer, Inc.; "The Pharmacia Group," which includes Pharmacia Corp. and Pharmacia & Upjohn, Inc.; "The Schering-Plough Group," which includes Schering-Plough Corp. and Warrick Pharmaceuticals Corp.; "The Sicor Group," which includes Sicor, Inc., Gensia, Inc., and Gensia Sicor Pharmaceuticals, Inc.; TAP Pharmaceutical Products, Inc.; and Watson Pharamaceuticals, Inc.

² The Amended Master Consolidated Complaint (the "AMCC") pleads causes of action under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1962(c),(d); Section 16 of the Clayton Act, 15 U.S.C. § 26; the Sherman Act, 15 U.S.C. § 1; the antitrust statutes of 22 states; state consumer protection statutes of 11 states; and civil conspiracy

the Defendant pharmaceutical manufacturer companies move to dismiss.

After hearing, the Court ALLOWS IN PART and DENIES IN PART the motion to dismiss the claims that the pharmaceutical companies violated the Racketeer Influenced and Corrupt Organizations Act ("RICO") and antitrust law. Among other things, the Court holds that Plaintiffs have set forth sufficient facts to state claims concerning: (1) the alleged RICO enterprises between the pharmaceutical manufacturers and four pharmacy benefit managers ("PBM's") with the common objective of promoting fraudulent AWP's; (2) the alleged price-fixing conspiracy of the Together Card Program Defendants in violation

law. The AMCC also seeks declaratory relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202. Plaintiffs bring this action on behalf of themselves and two classes:

[1] The AWP Payor Class:

All persons or entities who, for purposes other than resale and during the Class Period, paid any portion of the purchase for a prescription drug manufactured by a Defendant Drug Manufacturer (as identified in Appendix A) at a price calculated by reference to the published AWP during the Class Period.

[2] Sub-Class: The PBM Third-Party Payor Class:

All Third-Party Payors that, during the Class Period, contracted with a PBM to provide to its participants a prescription drug manufactured by a Defendant Drug Manufacturer and identified in Appendix A.

(¶ 595.)

of the antitrust laws; and (3) RICO claims involving multi-source drugs.

II. DISCUSSION

Plaintiffs allege three primary paradigms that accomplish this fraud. First, Plaintiffs allege that each Defendant artificially raises its published AWP's to benefit medical providers (like doctors). The "spread" between the actual cost of the drug and the AWP encourages providers to use that Defendant's drugs at the expense of the beneficiaries of Medicare Part B who make co-payments.³ Second, Plaintiffs allege that each Defendant increases AWP's and provides other fraudulent kickbacks, discounts and rebates to encourage pharmacy benefit managers to put its drugs on their formularies. Third, Plaintiffs allege that certain Defendant manufacturers participate in an antitrust and RICO conspiracy through a discount drug program, the Together Rx Program. The Defendants use this program to "raise, fix, maintain and/or stabilize the AWP of the Together Card Drugs," thereby raising the prices paid by the elderly, uninsured participants as well as by non-participants who also pay for those drugs based on AWP.

A. RICO

³ The Defendants do not address separately this paradigm, but they make arguments under Rule 9(b) in the context of the second paradigm that are applicable to both the first and second paradigms.

Plaintiffs allege that Defendants engaged in a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c) by establishing the fraudulent AWP pricing scheme through the use of interstate mails and wire communications. To state a RICO claim under § 1962(c), a plaintiff must allege four elements: "(1) conduct; (2) of an enterprise; (3) through a pattern; (4) of racketeering activity."⁴ See Libertad v. Welch, 53 F.3d 428, 441 (1st Cir. 1995). While pleadings are to be construed liberally, "a greater degree of specificity is required in RICO cases." Bessette v. Avco Fin. Servs., Inc., 130 F.3d 439, 443 (1st Cir. 2000).

Defendants argue that the RICO claims must be dismissed for five reasons: (1) Plaintiffs do not plead a viable enterprise; (2) Defendants did not conduct or participate in the conduct of any enterprise; (3) Defendants' actions were not the proximate cause of the Plaintiffs' injuries; (4) Plaintiffs failed to allege facts sufficient to satisfy Federal Rule of Civil Procedure 9(b); and (5) Plaintiffs' multi-source drug allegations

⁴ 18 U.S.C. § 1962(c) (2000) provides:

It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity

do not make sense.

1. Enterprises

Plaintiffs allege two types of enterprises. The first type is the Manufacturer-Publisher enterprise between each drug manufacturer and each of the publishers printing the AWP data. The second type is the Manufacturer-Pharmacy Benefit Manager enterprise between each drug manufacturer and each PBM. Each type of enterprise will be discussed separately.

(a) The Manufacturer - Publisher Enterprises (Count I ¶¶ 624 - 628)

In Count I, Plaintiffs claim that the Defendant drug manufacturers engaged in an illegal pattern of racketeering activity wherein each manufacturer formed a separate association-in-fact enterprise with each of the companies that published the AWP's, and that each manufacturer conducted the affairs of its enterprises. The complaint identifies Thomson Medical Enterprise, First DataBank, Inc. and Facts & Comparisons, Inc. as the publishers. (¶ 622.) For example, Plaintiffs allege an enterprise between Abbott and Thomson Medical, which "is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating false and misleading AWP's", (b) "selling, purchasing, and administering" [drugs with AWP's to plaintiffs]

and (c) "deriving profits from these activities." (¶ 628(a).)

Defendants argue that these allegations do not suffice to plead an association-in-fact enterprise under the tests established by the First Circuit. See Pharm. I, 263 F. Supp. 2d at 182. The First Circuit has considered several factors in determining whether a RICO association-in-fact enterprise has been properly asserted: (1) whether the associates have a common purpose; (2) whether there is systematic linkage, such as overlapping leadership, structured or financial ties or continuing coordination; (3) whether there is a common communication network for sharing information on a regular basis; (4) whether the associates hold meetings and sessions where important discussions take place; (5) whether the associates wear common colors, signs or insignia to make the group identifiable; and (6) whether the group conducted common training and instruction. See id.

According to the AMCC, each manufacturer-publisher enterprise "has a systematic linkage because there are contractual relationships, financial ties, and continuing coordination of activities" between the participants and a "common communication network" through which the participants "share information on a regular basis." (See, e.g., ¶ 628.) The primary communication between the participants in each alleged enterprise is the sending of the allegedly fraudulent AWP's by

the manufacturer to the publisher for publication. (§ 625.) The AMCC alleges that the publishers know of the fraudulent nature of the reported AWP's (§ 626), but they publish the information anyway. The AMCC alleges that "each one of the Publishers was aware of the Defendant Drug Manufacturers' AWP scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme." (§ 212.) Finally, according to the AMCC, "[e]ach of the enterprises has the common purpose of perpetuating use of the AWP's": the manufacturers wish to push the spread to increase their market share, and the publishers have an economic incentive to publish without question the prices reported "because if they did not, the manufacturers could easily revert to the other methods of publishing prices or the publishers would have to independently investigate the AWP at significant expense." (§ 624.)

These allegations of an association-in-fact enterprise fall short in two ways. An enterprise must be "a group of persons associated together for a common purpose of engaging in a course of conduct." United States v. Tourette, 452 U.S. 576, 580 (1981). The participants, as described, do not share a common purpose more specific than that common to many human endeavors, the reaping of a profit. The publishers are indifferent as to whether the AWP spread exists or not; their financial interest lies in earning money through selling books listing numbers. The

spread is irrelevant to their financial well being.

Further, Plaintiffs do not cite sufficient facts to support the allegation that the publishers know of the fraudulent nature of the AWP's they publish. Plaintiffs rely on surveys by unnamed publishers undertaken prior to 1992 regarding unnamed drugs, but the allegations in the complaint relate to behavior beginning in 1991. They also point to reports on AWP inflation by Congressional bodies and government agencies, and a recent lawsuit brought by Defendant Dey seeking to force publishers to publish the AWP it reports rather than the true price of its drugs, after publishers lowered its AWP's following a Texas prosecution of Dey for AWP fraud. While some of these factors may support an inference that some publishers may have been aware of concerns by governmental entities about inflated AWP's, they are insufficient to draw a reasonable inference that each of the publishers knew of the fraudulent nature of the AWP's for the identified drugs.

Plaintiffs further insist that "each of the manufacturer-publisher enterprises has a common purpose of perpetuating the use of AWP's as a benchmark for reimbursement in the pharmaceutical industry" (§ 624), thus skirting the issue of whether the publishers knew of the fraud. It is true that the use of AWP as a pricing benchmark may be a common objective, and the members of an enterprise do not have to share all objectives

so long as they have one in common. See, e.g., United States v. London, 66 F.3d 1227, 1244 (1st Cir. 1995) (holding that there was a common or shared purpose animating the enterprise, a bar, check-cashing business and an individual engaged in gambling: profiting from the bookmakers who were engaged in illegal gambling). However, without a shared illegal purpose to defraud, the shared innocent objective of using AWP as a published benchmark would not support a claim of a RICO enterprise. See Blue Cross v. Smithkline Beecham Clinical Labs., Inc., 62 F. Supp. 2d 544, 549 (D. Conn. 1998) (dismissing RICO complaint for insufficient allegations of a common purpose to defraud).

Second, even if the common "reaping-a-profit" objective were to suffice, the AMCC contains only conclusory allegations concerning systematic linkages and ascertainable structures. Essentially, Plaintiffs have merely parroted language from Pharm. I dismissing a similar claim in the initial master complaint. The only systematic linkage or structured or financial ties described with some detail in the AMCC are the contracts for the publishing of the AWP's; there are no allegations of a common command structure or any considered response to evolving conditions. Allegations of a common communication network beyond the sending of AWP information to be published are barebones: there are no common communications alleged beyond those that would be exchanged by parties to an arms-length contract. The

Plaintiffs do not attempt to allege the remaining factors (meetings, joint training, etc.) relevant to a determination of whether an association-in-fact existed. The publishers' printing of fraudulent AWP's under a contract with the manufacturers does not constitute an enterprise.

(b) The Manufacturer - PBM Enterprises
(Count II ¶¶ 651 - 661)

In Count II, Plaintiffs allege multiple associations-in-fact, each consisting of: (1) a PBM that, acting as a middleman between drug manufacturers and end-payors, administered purchases of a defendant manufacturer's drugs and billed end-payors based on the reported AWP and (2) a defendant drug manufacturer. (¶ 651.) The four named PBM's are: Advance PCS, serving 75 million health plan members; Caremark Rx, Inc., with \$5.6 billion in revenues in 2001; Express Scripts, Inc., the third-largest PBM in America; and Medco Health Solutions, Inc., a wholly-owned subsidiary of Merck. (¶ 650.) For example, the AMCC alleges an Abbott-Caremark Rx Enterprise. (¶ 661(a).)

According to Plaintiffs, PBM's, with the knowing assistance of the manufacturers, have engaged in hidden profit-making schemes falling into three general categories: (1) garnering rebates and other "soft dollars from drug manufacturers that the PBM's, to a large extent, keep without disclosing to the health plans the true amounts of the rebates"; (2) pocketing "secret

spreads" between actual drug costs and the prices charged to health plans and their members; and (3) keeping "secret discounts" provided by the drug manufacturers in association with the PBM's mail-order operations. (¶ 654.)

The paradigms here are somewhat different from the paradigm in the Medicare Part B context, discussed in Pharm. I. First, the AMCC alleges that the PBM benefits because it pockets the spreads between the published AWP's for brand-name drugs, which it uses to calculate the rates it charges to end-payors (e.g., AWP minus 13 percent), and the actual prices which it pays the retail pharmacies (e.g., AWP minus 15 percent). (See ¶ 171.) Second, there is a "spread" in PBM mail-order operations in which the PBM acts as a pharmacy between the published AWP price and the actual acquisition cost. (Id.) Finally, the PBM pockets spreads in the mail-order context in which a third-party "repackager" is used between the rates charged to end-payors and the rates paid to the repackagers. (Id.)

The "spreads" motivate the PBM's to put the brand-name drug on a formulary: the greater the AWP inflation, the greater the profit to the PBM from the spread. (Id.) Each manufacturer benefits from a spread because it encourages PBM's to sell that manufacturer's drug, rather than a competitor's.

Alleged communications between PBM's and the manufacturers include, *inter alia*: (1) marketing materials about the AWP's for

brand-name drugs sent from manufacturers to PBM's; (2) written representations of the AWP's sent by the manufacturers; (3) "thousands of written and oral communications discussing, negotiating and confirming the placement of a Defendant drug manufacturer's drug on a particular PBM's formulary"; and (4) written communications, including checks, relating to rebates, kickbacks and other financial inducements. (§ 666(a)-(i).) Additionally, salespersons from manufacturers regularly meet with PBM's in order to promote their products and the fraudulent AWP scheme. (§§ 664, 667(e).) Plaintiffs allege that Defendants controlled, *inter alia*, the setting of the AWP's, the distribution of marketing material used to inform the PBM's of the benefits of using AWP's, and the affairs of the PBM's by providing rebates and administrative fees in exchange for the PBM's use of a particular manufacturer's AWP's. (§ 667.)

These allegations provide a plausible common fraudulent purpose (a falsely-inflated AWP) and describe systematic linkages, common communication networks, and regular meetings among associates. It is true that Plaintiffs have not alleged specific communications for each enterprise, but courts have recognized that relaxation of pleading requirements is permitted where information is in a defendant's sole possession. See, e.g., Efron v. Embassy Suites (P.R.) Inc., 223 F.3d 12, 16 (1st Cir. 2000). Such relaxation is particularly appropriate here

where most of the Defendants have conceded that AWP's represent only an "undiscounted sticker price" that has no direct relation to the actual average price they charge for their drugs and that this is a widespread pricing and reporting practice. Pharm. I, 263 F. Supp. 2d at 180.

**2. Conduct or Participate in the Conduct
(Manufacturer - PBM Enterprises)**

Defendants argue that the AMCC makes insufficient allegations that each manufacturer conducted or participated in the conduct of the manufacturer - PBM enterprises. The "conduct or participate in the conduct" portion of § 1962(c) "requires some participation in the operation or management of the enterprise itself." Reves v. Ernst & Young, 507 U.S. 170, 176 (1993). "An enterprise is 'operated' not just by upper management but also by lower-rung participants in the enterprise who are under the direction of upper management. An enterprise also might be 'operated' or 'managed' by others 'associated with' the enterprise who exert control over it as, for example, by bribery." Id. at 184 (footnote omitted). See United States v. Shifman, 124 F.3d 31, 36 (1st Cir. 1997) (holding that debtor who referred persons to loan shark in exchange for debt relief or fees conducted or participated in the conduct of loan sharking enterprise); Aetna Cas. Sur. Co. v. P & B Autobody, 43 F.3d 1546, 1559 (1st Cir. 1994) (holding that operation or management test

required a "degree of direction" which can be direct or indirect).

Defendants argue that, at best, the AMCC alleges that they were simply conducting their own affairs, not participating in the enterprises. As noted above, the AMCC alleges that the Defendants were not simply acting legally to promote their products, but rather promoted the fraudulent AWP scheme. By directing the affairs of each enterprise through kickbacks and other financial incentives to PBM's, the Defendants sought to take advantage of an honor system established for price reporting to promote a fraudulent pricing scheme.

3. Causation

"When a plaintiff attempts to base a civil RICO claim on § 1962(c), that claim cannot succeed unless the injuries of which the plaintiff complains were caused by one or more of the specified acts of racketeering." Camelio v. Am. Fed'n, 137 F.3d 666, 669 (1st Cir. 1998) (citing Miranda v. Ponce Fed. Bank, 948 F.2d 41, 46-47 (1st Cir. 1991)). "[M]erely proving that the alleged predicate acts were a 'cause in fact' of plaintiff's injuries will not be sufficient. Instead, § 1964(c) requires proof that at least one of the defendant's predicate acts was the proximate cause of the plaintiff's injuries." Id. (citing Holmes v. Sec. Investor Prot. Corp., 503 U.S. 258, 268 (1992)).

In Holmes, the Supreme Court applied three policy tests to

support its finding that the defendant's actions were not the proximate cause of the plaintiff's injuries: first, how difficult it is "to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent factors"; second, whether holding the defendant liable "would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries"; and third, whether "the need to grapple with these problems is simply unjustified by the general interest in deterring injurious conduct, since directly injured victims can generally be counted on to vindicate the law as private attorneys general." Holmes, 503 U.S. at 269-70.

Here, Defendants argue that the alleged predicate acts are not the proximate cause of Plaintiffs' alleged injuries, for there are intervening acts between Plaintiffs' alleged injuries and the alleged acts of the Defendants. Specifically, Defendants note that the alleged misrepresentations were made to third-party publishers, not Plaintiffs; that the prescribing doctors set their own charges under Medicare; that numerous government actors, including Congress and carriers, chose to base their reimbursements on AWP; and finally, that any injury arising from a Manufacturer-PBM enterprise was not proximately caused by the Defendants, but rather by the PBM's or the Plaintiffs themselves.

The Defendants' arguments are not persuasive. In the private, end-payor context, the harm alleged by Defendants' alleged actions is visited directly upon the end-payor Plaintiffs, as they have paid directly for the named drugs based on the AWP's. Similar arguments about intervening causes between the setting of an AWP by a defendant and injuries to plans and individual co-payors were recently rejected as "border[ing] on the frivolous," In re Lupron Marketing and Sales Practices Litig., 295 F. Supp. 2d 148, 175 (D. Mass. 2003) (Stearns, J.), for "the argument ignores . . . the corollary requirement that the intervening act be unforeseeable and completely independent of any act undertaken by the original actor," id., a requirement not met in this case.

The conclusion that proximate cause exists is supported by the reasoning set forth in Holmes: the Defendants do not argue that there would be any particular difficulty in allocating damages; there are no other victims that will be sharing in the amounts claimed by Plaintiffs; and as the Plaintiffs are the ones directly injured, no other party is better placed to vindicate their interests.

4. Rule 9(b)

Defendants challenge the sufficiency of Plaintiffs' allegations under Rule 9(b) on numerous bases: (1) Plaintiffs have not identified the time, date and place of specific

statements between PBM's and manufacturers; (2) Plaintiffs have not linked particular drugs to particular PBM's; (3) Plaintiffs have not identified the prices they paid for each drug (thus allowing for a calculation of the "spread" in some cases) or the mechanisms within their contracts for calculating prices; (4) the allegations of volume discounts, rebates, credit memos, and the like are devoid of particulars; (5) Plaintiffs fail to specify the states in which drugs were purchased; (6) certain Plaintiffs, including the associations, did not allege the purchase of any drugs from certain Defendants; (7) Plaintiffs have failed to allege competitors for each drug; and (8) Plaintiffs do not allege that certain drugs were purchased under Medicare Part B.

In Pharm. I, the Court held that in light of the detailed fraudulent scheme alleged, the plaintiffs' allegations were sufficient with respect to "any drug identified in the complaint together with the allegedly fraudulent AWP published by a named defendant for that drug." 263 F. Supp. 2d at 194. The Court instructed that if plaintiffs were to file an amended complaint, "plaintiffs shall clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug." Id.

With respect to most Defendants, the Court finds that

Plaintiffs in the AMCC have pled allegations concerning the fraudulent scheme with enough specificity to comply with the requirements of Rules 9(b) and 8(a). See Franklin ex rel. v. Parke-Davis, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (Saris, J.) (“[W]here the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible. Courts facing similar claims under the False Claims Act have not placed the bar so high as to require pleading with total insight.”). In the AMCC, Plaintiffs describe extensively the factual investigations undertaken that formed the bases of Plaintiffs’ allegations, and in so doing identify particular allegedly-fraudulent conduct on the part of each Defendant, except one. (See ¶¶ 155 - 157 (describing government investigations); 187 (chart displaying spreads calculated by Department of Justice for eleven defendants); 200 - 540 (descriptions of varying specificity by particular defendant of pricing mechanisms, government investigations, internal documents identifying spread, and related items).) The amendments to the original complaint allege the particular drugs involved, and the AWP’s for those drugs. Compare Pharm. I, 263 F. Supp. 2d at 193-94.

The Court has examined each motion to dismiss filed by individual Defendants. After a review of Defendant-specific briefs, the Court rules as follows:

1. The claims by a Plaintiff association against a Defendant manufacturer are dismissed unless a member of that association is alleged to have purchased a drug from that Defendant.

2. The Court continues to defer ruling on the juridical linkage doctrine as that issue is more properly resolved in the context of class certification. See Payton v. Kane, 308 F.3d 673, 679-80 (7th Cir. 2002) (holding that a court should consider "issues of class certification prior to issues of standing" and pointing out that once a class is properly certified "standing requirements must be assessed with reference to the class as a whole, not simply with reference to the individual named plaintiffs"). Accordingly, so long as there is one named Plaintiff who purchased a drug from a Defendant, the Court will not dismiss the claims of fraud involving other drugs manufactured by that Defendant even if none of the named Plaintiffs purchased that particular drug. The Court declines the invitation at this early stage of the litigation to evaluate intricate arguments involving standing (for example, whether a plaintiff who has standing with respect to a Medicare Part B drug has standing to represent a purchaser of a drug under a private plan), although these issues may be appropriate in a typicality analysis under Fed. R. Civ. P. 23(a)(3).

3. In light of the allegations and concessions concerning

an industry-wide practice of inflating AWP's, the Court rejects arguments that Plaintiffs must allege a specific spread for each drug, so long as sufficient facts were alleged to infer a fraudulent scheme by each particular Defendant manufacturer (i.e., government investigations concerning that company, internal company documents, specific alleged fraudulent spreads on other drugs manufactured by that company and the like). The allegations not meeting this standard are discussed below.

4. The Court dismisses the claims regarding Viramune as it was apparently not manufactured by the Boehringer Group.

5. The Court dismisses Hoffman-LaRoche on the ground that there are insufficient allegations to support a claim of a fraudulent scheme. While industry-wide practices are relevant, this is essentially a guilt-by-association claim as there are no allegations concerning government investigations, internal documents or specific fraudulent spreads relating to this particular company. Defendant Hoffman-La Roche is the only Defendant for which no examples of allegedly-incriminating communications, fraudulent pricing, or government investigations were given. Plaintiffs explain that statements pertaining to Hoffman-La Roche's drug Kytril are detailed in the AMCC section pertaining to a competitor, the GSK Group. GSK allegedly sold Kytril to Hoffman-La Roche, and the AWP of Kytril has not decreased since the sale. (See ¶¶ 386 - 404 (citing documents

discussing benefits of spread).) I agree with Hoffman-La Roche that this pleading implicating another defendant is not particular enough to infer that Hoffman-La Roche engaged in racketeering.

Plaintiffs further argue that under First Circuit precedent, the proper course is to permit discovery, noting that unlike the other Defendants, Hoffman-LaRoche has never been subject to discovery. See New England Data Serv., Inc., v. Becher, 829 F.2d 286, 290-91 (1st Cir. 1987) ("[W]here, for example the specific allegations of the plaintiff make it likely that the defendant used interstate mail . . ., and the specific information as to use is likely in the exclusive control of the defendant, the court should make a *second* determination as to whether the claim as presented warrants the allowance of discovery and if so, thereafter provide an opportunity to amend the defective complaint."); but see Feinstein v. Resolution Trust Corp., 942 F.2d 34, 44 (1st Cir. 1991) (noting that "[a]llthough *Becher* may in certain circumstances give a plaintiff a second bite at the apple, its generous formulation is not automatically bestowed on every litigant").

Here, the Court makes the second determination that discovery is not warranted. Unlike in Becher, where the complaint contained other allegations of particular facts with regard to the defendants, 829 F.2d at 287, no specifics have been

alleged as to the conduct of Hoffman-LaRoche. Therefore, Hoffman-La Roche's motion to dismiss is ALLOWED.

6. The Court shall allow discovery to proceed with respect to B. Braun of America. Plaintiffs must respond to the issues of personal jurisdiction and whether the service of B. Braun of America relates back to the service of B. Braun Medical, Inc. by August 24, 2004.

5. Multi-source Drugs

In Pharm. I, the Court dismissed without prejudice plaintiffs' claims relating to multiple-source (including generic) drugs because the allegations were not specific with respect to such drugs and they "do not fit the paradigm described in the complaint." 263 F. Supp. 2d at 194 n.11.

In the AMCC, Plaintiffs allege that AWP fraud is "most exacerbated for generic drugs or for brand name drugs for which there are biological or therapeutic equivalents." (¶¶ 179-190.) They further allege that the AWP fraud affects private end-payors as well as the Medicare Part B program. According to the Plaintiffs, in the private payor arena, generic drug reimbursement is determined either in the same manner as for brand-name drugs (i.e., a certain percentage "discount" off of the AWP) or is based on the amount specified as the maximum allowable cost or "MAC." MAC prices or reimbursement rates are a schedule of pricing for generically equivalent drugs based upon

the AWP's of competing generic drug manufacturers. The federal government issues a MAC price for generic products that have three or more manufacturers or distributors on the market. PBM's sometimes utilize this MAC reimbursement publication, and sometimes calculate a maximum allowable cost based on their own formulae, which utilize the list average wholesale prices of competing generic drug manufacturers. The use of a maximum allowable cost based on the list average wholesale price is termed in the industry as the "average average wholesale price."

In the public payor arena under Medicare Part B, multi-source drugs or biologicals are reimbursed on the basis of the lesser of the median AWP of all of the generic forms of the drug or biological, or the lowest brand-name product AWP, with the resulting price confusingly being also termed "AWP". (¶ 149 (citing Program Memorandum AB-99-63 (Sept. 1999)).)

The raising of an individual Defendant's reported AWP for a multi-source drug can (but does not necessarily) raise the median AWP at which the generic drug is reimbursed. Moreover, while any one generic manufacturer can only affect the median generic reimbursement for AWP for a product, rather than directly affecting its own drug's reimbursement. Defendants still benefit from the spread between the median AWP and the actual prices paid. (¶ 186.) According to the AMCC, "[t]he natural and expected result of this 'leap frogging' of increasing AWP's is

that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs." (¶ 187.) For example, Baxter publishes the AWP for Sodium Chloride at \$928.51, while the DOJ determined that the actual AWP was \$1.71, a percentage spread of 54,199%. (¶ 187, chart.)

Defendants argue that the allegations regarding the underlying fraudulent scheme for multi-source drugs are insufficient under Rule 9(b). Defendants reason that they have no motive to compete by increasing the "spread" between the average wholesale price of multi-source drugs and the actual price of such drugs to providers, because Medicare Part B pays for multi-source drugs at "the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological." 42 C.F.R. § 405.517 (2003). No one drug maker could gain an advantage by leapfrogging the AWP over a competitor's, Defendants argue, as reimbursement is based on the median. For similar reasons, there is no reason to compete with regard to non-Medicare Part B, multi-source drugs, which are reimbursed based on MAC's.

Plaintiffs respond that prices of multi-source drugs are often based on AWP in the private payor context, giving drug makers the same incentive to increase AWP. In any event, at this

stage of the proceeding, Plaintiffs are not required to prove motive, see Fed. R. Civ. P. 9(b), and the allegations are specific enough to accord with Fed. R. Civ. P. 9(b).

B. State Civil Conspiracy Claims, State Consumer Protection Statutes

The Court declines to reach the merits of the motions to dismiss the multiple state law claims, which were briefed inadequately. The Court will address these state law claims at the summary judgment stage.

C. Together Rx Claims

Plaintiffs claim that Defendants illegally manipulate AWP's through the creation of a discount card program - the Together Rx Program - to share price data, fix prices and stave off public inquiry.

In response, Together Rx LLC ("Together Rx") and its member companies⁵ (collectively, the "Together Rx Defendants") move to dismiss Counts V (Section 16 of the Clayton Act, 15 U.S.C. § 26), VI (Section 1 of the Sherman Act, 15 U.S.C. § 1), VII (various state antitrust statutes), VIII (RICO, 18 U.S.C. § 1962(c), (d)) and X (Civil Conspiracy) of the AMCC, all counts directed against

⁵ The eight member companies of Together Rx are: Abbott Laboratories; AstraZeneca Pharmaceuticals, L.P.; Aventis Pharmaceuticals, Inc.; Bristol-Myers Squibb Company; SmithKline Beecham Corporation d/b/a GlaxoSmithKline; Janssen Pharmaceutical Products, L.P. and McNeil-OPC, Inc. (both affiliates of Johnson & Johnson); and Novartis Pharmaceuticals Corporation.

the Together Rx Program.⁶

The AMCC makes the following allegations regarding the Together Rx Program. In 2001 or 2002, the Together Rx Defendants agreed to establish a program to offer drug discounts to older, uninsured and poor consumers. (¶¶ 542-544.) To implement the program, they fixed the AWP "spread" (the difference between published AWP and the wholesale acquisition cost or "WAC") on over 170 widely-prescribed brand-name drugs purchased through the program ("Together Card drugs"). (¶ 544.) The Together Card Program has caused Plaintiffs and the nationwide end-payor Together Card class to pay more for Together Card drugs. (¶ 545.) Plaintiffs therefore allege a conspiracy "to raise, fix, maintain and/or stabilize" the AWP spread. (¶ 545.) Another purpose of the program, according to the AMCC, was to allow the Together Rx Defendants to respond to public pressure over escalating drug costs. (¶ 550.) The Together Rx Program was launched in April of 2002. (¶ 560.)

As proof of this scheme, Plaintiffs allege that the Together Rx Defendants simultaneously and uniformly increased the spreads between posted AWP's and WAC's on over 80% of their Together Card drugs in order to provide an incentive to others in the distribution chain to participate in the program, an incentive

⁶ Defendants address the non-antitrust claims only summarily and the Court declines to dismiss them.

that operated to the detriment of end-payors (like insurance companies and health plans). (§§ 588-591.) The effectively-simultaneous timing of the Together Rx Defendants' increases in AWP spreads is unprecedented in terms of the number of products per manufacturer and number of manufacturers within the pharmaceutical industry. (§ 592.) Notably, each of the seven Together Rx Defendants achieved precisely a 25% spread following the formation of the program as shown below. (§ 591.)

Together Card Defendant	Together Card Drug	AWP Before Alliance	WAC Before Alliance	AWP Spread Before Alliance	AWP After Alliance	WAC After Alliance	AWP Spread After Alliance
Abbott	Biaxin 500 mg #60	\$396.72	\$334.08	18.8%	\$437.98	\$350.38	25%
AstraZeneca	Prilosec 40 mg #1000	\$6,171.66	\$5,143.04	20%	\$6,621.67	\$5,297.34	25%
Aventis	Allegra 60 mg #100	\$118.26	\$98.63	20%	\$123.29	\$98.63	25%
BMS	Tequin 400 mg #100	\$818.86	\$682.27	20%	\$895.48	\$716.38	25%
GSK	Combivir #100	\$1,241.26	\$1,034.38	20%	\$1,370.55	\$1,096.44	25%
J&J (Janssen)	Risperdal 2 mg #500	\$2,320.10	\$1,933.42	20%	\$2,535.20	\$2,028.16	25%
Novartis	Exelon 2 mg/ml	\$246.96	\$205.80	20%	\$267.29	\$213.83	25%

The total percentage of all Together Card drugs manufactured by the Together Rx Defendants with an AWP spread greater than 24% increased from 25.5% in 2000, to 92% by 2002. (§ 590.) Plaintiffs contend that "the Together Card Defendants' immediate

increase of the AWP spread on Together Card drugs diluted any meaningful discount for the relatively small number of eligible consumers and raised the price for other consumers significantly beyond what was charged prior to the Together Card Defendants' formation of the alliance." (¶¶ 10, 593.)

Defendants contend that all conspiracy counts should be dismissed because the factual allegations "make no economic sense" and because Plaintiffs lack standing. The standard governing motions to dismiss pursuant to Fed. R. Civ. P. 12(b)(6) applies to an antitrust claim. See Caribe BMW, Inc. v. Bayerische Motoren Werke Aktiengesellschaft, 19 F.3d 745, 748 (1st Cir. 1994). In antitrust cases "where the proof is largely in the hands of the [defendant], dismissals prior to giving the plaintiff ample opportunity for discovery should be granted sparingly." Hosp. Bldg. Co. v. Trs. of the Rex Hosp., 425 U.S. 738, 746 (1976). However, sparingly does not mean never. A plaintiff must allege sufficient facts in order to state each element of the antitrust violation. See C.R. Bard, Inc. v. Med. Elecs. Corp., 529 F. Supp. 1382, 1389 (D. Mass. 1982).

1. Sufficiency of Antitrust Allegations

Section One of the Sherman Act prohibits "[e]very contract, combination . . . or conspiracy, in restraint of trade." 15 U.S.C. § 1 (1997). That language establishes two prerequisites for a Section 1 claim. Podiatrist Ass'n v. La Cruz Azul de

Puerto Rico, Inc., 332 F.3d 6, 12 (1st Cir. 2003). First, the plaintiff must show concerted action between two or more separate parties. Monsanto Co. v. Spray-Rite Serv. Corp., 465 U.S. 752, 761 (1984). Second, the plaintiff must show that such action unreasonably restrains trade. NYNEX Corp. v. Discon, Inc., 525 U.S. 128, 133 (1998). A small set of acts constitute per se violations of Section 1 because the acts are regarded by the Court "as sufficiently dangerous and so clearly without redeeming value that they are condemned out of hand, that is, without a showing of wrongful purpose, power or effect." Eastern Food Servs., Inc. v. Pontifical Catholic Univ. Servs., Inc., 2004 WL 110844, at *2 (1st Cir. Jan. 20, 2004). Thus, "proof of the defendant's power, of illicit purpose and, of anticompetitive effect" are irrelevant. U.S. Healthcare, Inc. v. Healthsource, Inc., 986 F.2d 589, 593 (1st Cir. 1993).

Price fixing agreements qualify for the per se label. "Stabilizing prices as well as raising them is within the ban of § 1 of the Sherman Act." United States v. Container Corp. of Am., 393 U.S. 333, 337 (1969). "Under the Sherman Act a combination formed for the purpose and with the effect of raising, depressing, fixing, pegging, or stabilizing the price of a commodity in interstate or foreign commerce is illegal per se." United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 223 (1940).

Defendants' core argument is that Plaintiffs have not

alleged an economically plausible theory because Defendants have no economic incentive to collude to increase AWP's or the "AWP spread" on Together Rx drugs. The Supreme Court has held that "if the factual context renders [plaintiff's] claim implausible - if the claim is simply one that makes no economic sense - [plaintiff] must come forward with more persuasive evidence to support their claim than would otherwise be necessary."

Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). Following this precedent, courts have dismissed antitrust conspiracy claims where a plaintiff has presented nothing more than "unlikely speculations." DM Research, Inc. v. College of Am. Pathologists, 170 F.3d 53, 56 (1st Cir. 1999) (holding that allegations of a "conspiracy" or "agreement" "might well be sufficient in conjunction with a more specific allegation - for example identifying . . . a basis for inferring a tacit agreement," but reasoning that "the discovery process is not available where, at the complaint stage, a plaintiff has nothing more than unlikely speculations"). See also Car Carriers, Inc. v. Ford Motor Co., Inc., 745 F.2d 1101 (7th Cir. 1984) (holding that "a complaint must contain either direct or inferential allegations respecting all the material elements necessary to sustain a recovery under some viable legal theory").

Defendants argue that the Together Rx transactions alleged by Plaintiffs make no economic sense. In one type of transaction

specifically alleged in the AMCC, Novartis offered its drugs to Together Rx Card holders with incomes less than \$24,000 for a flat fee of \$12 per prescription. The difference between \$12 and the price the pharmacy charges for the drug is the amount of the subsidy provided by Novartis. (§ 558.) Defendants argue that an increase in AWP spread would actually hurt each drug company, which would have to pay more in subsidies to each retail pharmacy with no offsetting increase in revenues. In another type of Together Rx transaction alleged by Plaintiffs, the manufacturer pays a specific dollar subsidy and the cardholder pays the difference between that subsidy and the pharmacy's selling price. With respect to this type of transaction, Defendants point out, increasing the spread between WAC and AWP does not increase the revenue the Defendant manufacturer receives. Therefore, Defendants argue, the theory behind the entire alleged conspiracy is nonsensical.

Plaintiffs argue that a conspiracy which stabilizes a volatile market and fixes both prices and discounts is a classic example of a horizontal, per se violation of the Sherman Act. The AMCC alleges that the Together Card Program was created, at least in part, to stave off congressional and public scrutiny. (§ 550.) Moreover, from an economic viewpoint, Plaintiffs argue, increasing the AWP spread on the 170 drugs would shift the financial burden of the Together Card Program onto non-Together

Rx third party end-payors and create "spread dollars" for others in the distribution chain (like pharmacies and wholesalers). In other words, it functions as a cross-subsidy placed on end-payors to incentivize these other entities to participate in the program.

In light of the extremely complex nature of drug pricing, the record is inadequate for fully evaluating either argument. It is worth pointing out, however, that Defendants have not given a plausible reason why they all simultaneously created the same spread for market based reasons. At this stage, with all reasonable inferences drawn in their favor, Plaintiffs have not alleged an implausible economic or political theory.

Defendants also argue that parallel price movements alone are insufficient to establish a conspiracy. Clamp-All Corp. v. Cast Iron Soil Pipe Inst., 851 F.2d 478, 484 (1st Cir. 1988) (finding that evidence "consisting of little more than" "follow-the-leader" price lists for virtually identical products "would not permit a finding of more than such individual, interdependent, price setting"). "Since mere parallel behavior can be consistent with independent conduct, courts have held that a plaintiff must show the existence of additional circumstances, often referred to as 'plus' factors, which, when viewed in connection with the parallel acts, can serve to allow a fact-finder to infer a conspiracy." Apex Oil Co. v. DiMauro, 822 F.2d

246, 253 (2d Cir. 1987). Such circumstances might include a common motive to conspire or a high level of inter-firm communications. Id. at 254 (citations omitted). See also Illinois Corp. Travel v. American Airlines, 806 F.2d 722, 726 (7th Cir. 1985) (explaining that "to show conspiracy indirectly the plaintiff must demonstrate that the firm is behaving in a way that is inconsistent with unilateral decisionmaking," i.e., that "the defendant acted in a way that, but for a hypothesis of joint action, would not be in its own interest").

The Plaintiffs' Together Rx allegations include more than mere parallel pricing. The AMCC alleges, for example, that the Together Rx Defendants joined the Together Rx program with the common motive of staving off Congressional and public scrutiny (§ 550) and that the Together Rx program facilitated the sharing of price information. (§ 546.) Moreover, the Together Rx Defendants simultaneously created identical AWP spreads on several widely-prescribed drugs, raising a reasonable inference of conspiracy. (§ 592.) Cf. Cayman Exploration Corp. v. United Gas Pipe Line Co., 873 F.2d 1357, 1361 (10th Cir. 1989) (affirming dismissal of horizontal price-fixing conspiracy claim where plaintiff "did not identify the alleged conspirators, when or how they functioned, or the nature and extent of [defendant's] participation in the alleged conspiracy"); Yellow Page Solutions, Inc. v. Bell Atlantic Yellow Pages, 2001 WL 1468168, at * 14

(S.D.N.Y. Nov. 19, 2001) (dismissing complaint where "plaintiffs do not allege, as they must" when or where any unlawful agreement was made, or by whom, or why the parties would enter into this agreement, or that uniform pricing policies are "anything other than independent, parallel conduct meant to maximize each party's own revenues"). The Together Rx Plaintiffs, by contrast, have alleged parallel movements, as well as sufficient "plus" factors to survive a motion to dismiss.

2. Standing

Plaintiffs bring their Together Card claims on behalf of the following proposed class:

All persons or entities in the United States and its territories who paid any portion of the purchase price for, or who reimbursed any portion of the purchase price of, a drug covered by the Together Rx Program on the basis, in whole or in part, on the published average wholesale price during the time period January 1, 2002 up to and including the present.

(¶ 604.) Defendants argue that Plaintiffs lack standing to assert their claims because no Plaintiff is enrolled in the Together Rx Program. The Plaintiffs assert they either paid for or were reimbursed for Together Card drugs, the prices of which were based on AWP. Therefore, Plaintiffs have standing to assert their claims.⁷ See RSA Media, Inc. v. AK Media Group, Inc., 260

⁷ The Court does not decide at this point whether Plaintiffs have standing to assert claims on behalf of elderly program

F.3d 10, 14 (1st Cir. 2001) ("Although we technically balance the six factors [articulated in Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519 (1983)] to determine if standing is appropriate, this Court has emphasized the causation requirements of that test."); Morales-Villalobos v. Garcia-Llorens, 316 F.3d 51, 55 (1st Cir. 2003) (overturning grant of motion to dismiss for lack of antitrust standing where plaintiff alleged but-for causation and direct injury and court found "no reason why . . . the injury to her would not be of the kind that antitrust laws are intended to address").

ORDER

Defendants' motions to dismiss the Amended Master Consolidated Complaint are **ALLOWED IN PART, DENIED IN PART**. The motion to dismiss Count I is **ALLOWED**. The motion to dismiss the other counts is **DENIED**. The Court dismisses Hoffman-LaRoche, the claims involving Viramune, and the claims by an association against a defendant from which none of its members purchased drugs. The stay of discovery as to multi-source drugs is lifted. Plaintiffs must respond to the jurisdictional and service issues with respect to B. Braun of America by August 24, 2004.

S/PATTI B. SARIS

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United States District Judge